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| 10/070,386 | 03/06/2002 | Manabu Watanabe | 2002-0275A | 2874 |
| 513 | 7590 | 07/13/2004 | EXAMINER | |
| WENDEROTH, LIND & PONACK, L.L.P. | | | MCKELVEY, TERRY ALAN | |
| 2033 K STREET N. W. | | | ART UNIT | |
| SUITE 800 | | | PAPER NUMBER | |
| WASHINGTON, DC 20006-1021 | | | 1636 | |

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

1/15

Office Action Summary

Application No.

10/070,386

Applicant(s)

WATANABE ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6-10, 12 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/02; 6/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-5, 11, and 13-18 in the reply filed on 4/23/04 is acknowledged.

Claims 6-10, 12, and 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/23/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11, 13, and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

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that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a promoter comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:1, nucleotide sequences having at least 70% homology to SEQ ID NO:1, modified nucleotide sequence of SEQ ID NO:1 having one or more mutations, a nucleotide sequence that hybridizes to SEQ ID NO:1 under stringent conditions, and fragments of any of the previous, wherein the nucleotide sequence has promoter activity. Although the nucleotide sequences are all originally based upon the structure of SEQ ID NO:1, there is no actual limitation to that structure because the claim is also drawn to sequences that are one or more mutations of SEQ ID NO:1 (and fragments thereof), which potentially encompasses any promoter (because any promoter can be made by one or more mutations from any sequence), although this does not appear to be intended by the applicant. Thus, the claims are actually drawn to a genus of compounds that is defined only by their function, having "promoter activity", which encompasses a huge genus of very different sequences. This is not a limitation to nucleotide sequences having a predictable structure because promoters in the art do not necessarily have a common, recognizable structure.

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To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is the starting structure of SEQ ID NO:1, which is a nucleotide sequence of 1378 base pairs, and which has promoter activity. There is no description of any of the particular nucleotides responsible for the promoter activity within SEQ ID NO:1, nor is there a description of particular nucleotides that can be altered or removed while retaining promoter activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompasses nucleotide sequences having at least 70% homology to SEQ ID NO:1, modified nucleotide sequence of SEQ ID NO:1 having one or more mutations, and fragments thereof, all of which encompass promoter sequences which have potentially many differences in structure from SEQ ID NO:1, but which are

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encompassed by the claimed invention when they retain promoter activity.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of promoters, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of

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written description for that broad class. The specification provided only the bovine sequence.

Therefore, only nucleotide sequences comprising SEQ ID NO:1, and nucleotide sequences that hybridize with a nucleotide sequence comprising SEQ ID NO:1 and which has promoter activity, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Regarding claim 13, the analysis set forth above is equally applicable to sequences based upon the terminator sequence of SEQ ID NO:2.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 11, and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, etc are limited to "a modified nucleotide sequence of SEQ ID NO:1 that has one or more modifications selected from a substitution, a deletion, an addition, and an insertion and has promoter activity". This phrase renders the claims vague and indefinite because the metes and bounds of the sequences encompassed by the phrase are unclear. On its face, the phrase seems to encompass any promoter sequence because any promoter sequence can be made from another based upon comprising any number of substitution, a deletion, an addition, and an insertion changes. However, from the specification it clearly appears that the applicants did not intend for the claims to read on any promoter (which obviously are not free of the prior art), but instead for the claimed promoters to be more closely related to the promoter sequence of SEQ ID NO:1. The metes and bounds of what the applicant intended for the claimed promoter, distinguished from claiming any promoter, are thus unclear and the claims are vague and indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

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Claims 1-5, 11, 13, and 15 are rejected under 35 U.S.C. § 101 because the claimed invention is drawn to non-statutory subject matter.

The preamble of the claims recites "A promoter ...", "the promoter according to ...", and "An expression vector comprising the promoter ...". Natural promoters that are not isolated or purified, and corresponding expression vectors having those promoters are products of nature that are not statutory subject matter because they fail to show the "hand of man" in their construction because they read on non-isolated promoters in natural genomes (the natural chromosome on which the promoter resides reads on expression vectors). Amending the claims to recite "An isolated promoter ..." (and having the expression vectors dependent thereon) would be remedial.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does

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submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

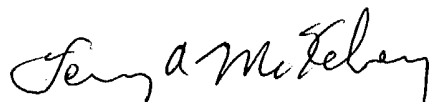
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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

July 11, 2004